



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0349]

Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report).” This guidance is intended to inform applicants of the conditions under which FDA will exercise its waiver authority to permit applicants to submit an International Conference on Harmonisation (ICH) E2C(R2) Periodic Benefit-Risk Evaluation Report (PBRER) in place of the ICH E2C(R1) Periodic Safety Update Report (PSUR), U.S. periodic adverse drug experience report (PADER), or U.S. periodic adverse experience report (PAER), to satisfy the periodic safety reporting requirements in FDA regulations. The guidance describes the steps applicants can take to submit the PBRER, and discusses the format, content, submission deadline, and frequency of reporting for the PBRER.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft

guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE
FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format (Periodic Benefit-Risk Evaluation Report).” We are issuing the draft guidance to describe the conditions under which FDA will exercise its waiver authority to permit the holders of approved new drug applications, abbreviated new drug applications, and biologics license applications (applicants) to use the reporting format of the PBRER to submit periodic safety reports for their marketed products. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions (the European Union, Japan, and the United States) and to enhance efficiency by reducing the number of reports generated for submissions to the regulatory authorities.

FDA’s postmarket safety reporting regulations require applicants to submit periodic safety reports in the form of a Periodic Adverse Drug Experience Report (PADER) (for drugs) or a Periodic Adverse Experience Report (PAER) (for biologics) (21 CFR 314.80(c)(2) and 600.80(c)(2), respectively). FDA has routinely granted waivers under 21 CFR 314.90(b) and 600.90(b) permitting applicants to submit an internationally harmonized Periodic Safety Update Report (PSUR) prepared in accordance with ICH E2C (see 62 FR 27470 (May 19, 1997) and 69

FR 5551 (Feb. 5, 2004)) instead of a PADER/PAER under conditions stated in the waiver. On November 15, 2012, the ICH Steering Committee signed off on the ICH harmonized guideline “Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)” and recommended that the PBRER format be adopted by the ICH regulatory bodies of the three regions. Therefore, the new and more comprehensive report format, the PBRER, has superseded the PSUR report format.

This guidance provides information on the steps applicants can take to submit a PBRER to the FDA in place of a PSUR, PADER, or PAER. The guidance discusses: (1) Applicants who have a waiver in place for their approved product to submit a PSUR instead of a PADER/PAER and (2) applicants who have not obtained a waiver and are currently submitting PADERs/PAERs as required under FDA regulations. Because the PBRER has replaced the PSUR as the ICH E2C harmonized postmarket safety report format, FDA is permitting applicants with an existing PSUR waiver to substitute the PBRER for the PSUR without submitting a new waiver request. This guidance describes the steps an applicant should take to submit the PBRER in place of the PSUR. For applicants who do not have a PSUR waiver in place for their approved application but would like to submit the PBRER in place of the PADER/PAER, this guidance provides information on how to submit a waiver request if they wish to do so.

This guidance describes the content, format, and submission deadlines applicants should follow when submitting the PBRER, as well as U.S.-specific appendices that should be submitted with the PBRER. It also explains how applicants can fulfill FDA’s annual reporting requirement while submitting a harmonized PBRER that covers a longer reporting interval. In addition, the guidance notifies applicants that they may submit requests to be waived of the quarterly reporting requirement and instead, to submit PBRERs on a 6-month basis.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on providing postmarket periodic safety reports in the ICH E2C(R2) PBRER format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

IV. The Paperwork Reduction Act of 1995

This draft guidance addresses information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information related to submission of waiver requests under §§ 314.90(a) and 600.90 have been approved under OMB control numbers 0910-

0001 and 0910-0308. In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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